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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,565	01/04/2002	Leland L. Bass	5964	3695

7590 02/28/2005

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EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,565

Applicant(s)

BASS, LELAND L.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 20-23 is/are allowed.
- 6) ☒ Claim(s) 1-19, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2005 has been entered.

2. Claims 6, 11, 15 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The sample is not a positively recited feature of the device and therefore what happens to it in the use of the device is not a further limitation of the structure of the device.

3. Claims 1- 19 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 12, it is not clear what structural limitation is imposed by the air pocket being claimed unless it requires that the upper portion be sealingly engaged by contacting an inner wall of the tube around a perimeter of the upper portion of the separator. If that is the case, then the air pocket provides no structural definition because that is how examiner has been treating the "a separator having an upper portion sealingly engaged" language of the claims. In other words the air pocket is an inherent feature of the structure as claimed and not a structural limitation. In claim 3, since the predetermined volume is already defined in claim 1 it is not clear what structural limitation is being claimed since the specimen is only present during use and not positively recited as an element of the device. Furthermore, it is not clear how the air pocket defines the volume of specimen to be expressed: the specimen fills the air pocket or the air pocket prevents specimen from entering that space below the separator and limits the amount of specimen. Additionally, relative to the expressing of a specimen in claims 3 and 12, examiner notes that there is no positively recited structure that would prevent fluid or other material that would be above the separator from being expressed and therefore it is not clear if there is any structural limitation associated with the expressed language. In claims 6, 11, 15 and 19 it is not clear what structural limitation is intended since applicant appears to be trying to claim a property of the method of using the device rather than

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the structure of the device. In other words it is not clear what if any further structural feature allows the stated functional language to occur. These four claims have been treated by examiner as not further limiting as outlined above.

4. For clarity purposes, examiner is treating claims 1 and 12 to include the following structural features. Claim 1 comprises a tube having a lower pipette portion with a passage therein and a separator with an upper portion sealingly engaged with an inner wall of the tube, the separator having a lower portion defining a passage and an end edge. Claim 12 adds limitations of a plug for sealing engagement in the pipette passage and a cap for sealingly closing an upper open end portion of the tube.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, and 5-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Swank (US 3,448,041). In the patent Swank teaches apparatus for treating blood prior to its use in transfusions. Particularly relevant to the instant claims are the structures shown in figures 3 and 7. As is illustrated in figure 3, the apparatus includes a vertically arranged tube (30) of glass or other easily sterilized material of sufficient length to provide the desired dwell time and capacity. At one end of the tube is an inlet port (32) through which the stored blood to be treated is introduced. At the other end is a pipette portion with passage therethrough (outlet port 34) that passes the treated blood ready for use. One or more separators (baffles 36) may be provided in the tube. This directs the flow of blood toward the longitudinal center of the tube, preventing channeling along the side walls and insuring effective treatment. Although the separator (baffle) may assume diverse shapes, it preferably comprises a truncated cone tapering inwardly in the downstream direction, having a central opening (a reduced lower portion defining a passage), and fused or glued to (sealingly engaged with) the inner side walls of the tube. The embodiment shown in figure 7 is readily disassembled for cleaning and sterilization, although alternatively it may be manufactured as an integral, sealed unit for discarding after a single use. The improved form of the apparatus accordingly includes a vertically arranged tube (70) of glass, plastic or

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other easily sterilized material. The upper end of the tube is open, but mounts a removable cap (72) that is fitted with a sealing O-ring (74) and provided with a central infeed connection (76). The central portion of the bore of tube is formed with an annular shoulder (78, tapered portion). The lower portion of the tube is formed with another annular shoulder (80) and a tapered chamber (82) to deliver the treated blood to a centrally located pipette portion (outfeed connection 84). A separator (baffle 86) having a central opening (88) seats (is sealingly engaged with) and is supported on shoulder 78. The upper surface of the baffle is conical and guides the raw blood through central opening, to locate it centrally of the tube for most efficient treatment.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballies (US 4,154,690) in view of Darling and Alspector (US 4,824,560) or Van Vlasselaer (US 5,474,687). In the patent Ballies teaches a device for use in blood centrifugation processes, said device comprising a centrifuge tube containing a substantially rigid separator element and said tube having walls of predetermined thickness and material of construction to enable flexing of only that portion of the tube wall coincident with said separator element, sufficient to enable passage of liquid by said separator element, in response to centrifugal force. The embodiments of figures 3-12 show a tube (2) having a pipette portion (19) extending from a lower end thereof. Figures 6 and 7 show a cap for the upper open end of the tube. Figure 7 also shows a plug (50) as part of a cap for the lower end of the tube. Figure 10 shows a tapered tube that has a decrease

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in the internal diameter of the bottom portion relative to the top portion. Ballies does not teach a separator that is fixed to provide a predetermined volume of fluid after centrifuging or a funnel shape for the separator.

In the paper Darling teaches a water separator. An even more efficient separator can be made if an internal funnel is inserted to conduct all of the condensate to the bottom of the tube. This is made of a piece of 6-mm. glass tubing flared at one end and inserted into a piece of cork. The cork is then force fit into the device.

In the patent Alspector teaches sedimentation classification of particulate material in liquid dispersion. The dispersion is centrifuged in a tubular vessel comprising at least two neighboring compartments communicating via at least one opening which Alspector teaches may be capillary. The lowermost compartment has a sealed bottom and the uppermost has an open upper end. Upon completion of the centrifugation a liquid fraction with dispersed particulate material is decanted from the uppermost compartment. The separator prevents backmixing that normally would be a problem if the separator were not present. Useful products may also be recovered from other compartments. The embodiments of figures 4-6 have compartments with defined volumes and allow that collection of multiple components or fractions that can be separated by centrifugation.

In the paper Van Vlasselaer teaches a constriction member (12) for use in a centrifuge tube. Particularly relevant to the instant claims are the shape of the member which a top surface that is slightly angled inwardly toward the opening in the constriction member. The bottom surface is taught as also being slightly angled (column 6 lines 12-18) although not shown in the figures. In the paragraph bridging columns 6-7 Van Vlasselaer teaches that the constriction may be either an insert or molded into the tube at the time the tube is formed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate fixed separation elements such as taught by Darling or Van Vlasselaer because of their recognized ability to separate components in a mixture during centrifugation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a separator designed to leave a fixed volume of fluid in the bottom of the tube as taught by Alspector or Van Vlasselaer because of the ability to collect a defined volume of material in the lower compartment as taught by Alspector or Van Vlasselaer. It would have been obvious to one

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of ordinary skill in the art at the time the invention was made to use shapes other than the funnel shape because as determined by the Court change in form or shape is an obvious engineering design (see *In re Dailey*, 149 USPQ 47 (CCPA 1976)).

9. Claims 20-23 are allowed because the art of record fails to teach or fairly suggest the structure of the claims.

10. Applicant's arguments filed January 12, 2005 have been fully considered but they are not persuasive. Relative to the art rejection examiner first points out that the claims are drawn to an apparatus which requires that the claimed structure is not anticipated by or obvious in view of the art applied. The rejected independent claims have been interpreted above to show applicant how the claims have been treated by examiner. Next, as applicant should readily recognize, most of the time a device can be used in multiple ways. The instantly claimed device is no different since it might be used for gravity settling or to pass fluids through under pressure as a pipette tip or as a chamber for causing turbulence in the liquid flowing through it. All of these methods of use are different from that which applicant discloses and one or more of these methods of use may not allow the formation of an air pocket as applicant has disclosed. Thus the manner in which the instantly claimed device is used and properties or characteristics of the material contained therein during use in a certain manner do not distinguish between the instant claims and a reference teaching the structure claimed. Thus the Swank reference, teaching a structure within the claimed structure, fully anticipates the structure. Another way of saying this is that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Relative to the instant rejected claims examiner notes that it appears applicant is able to claim the instant device of these claims in a manner that an interference with the Elkins patent (US 6,401,552) would be appropriate. Additionally, since there is already a patent issued with claims describing a device that is shown in both the instant figures and the figures of the patent,

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an interference may be the only way to get a patent that would cover a figure of the instant application that is covered by the patented claims. Thus to further prosecution examiner would suggest that applicant seriously consider the possibility of amending the rejected claims to provoke an interference.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to separation devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner's schedule is variable between the hours of about 6:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



February 24, 2005

ARLEN SODERQUIST
PRIMARY EXAMINER